Case 1:11-cv-08196-CM-JCF Document 262 Filed 09/19/14 Page 1 of 3

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September 19, 2014

VIA ECF & FACSIMILE 212-805-6326

The Honorable Colleen McMahon United States District Court Southern District of New York Daniel Patrick Moynihan U.S. Courthouse 500 Pearl Street, Chambers 1640 New York, New York 10007-1312

Re: United States ex. rel. Kester v. Novartis Pharmaceuticals Corp. et al., Civil Action No. 11-8196 (CM) (JCF)

Dear Judge McMahon:

Defendants CVS, Curascript and Accredo last night filed a letter on the alleged "futility" of Relator's reverse FCA allegations. Defendants make only one argument, namely that "an 'obligation' giving rise to a reverse FCA claim must be different than the mere failure to repay money the defendant received by making an affirmative false claim." CVS Ltr at 1. Defendants' arguments are wrong on the law, and they overlook what Relator's complaint alleges.

First, defendants overlook two important statutory amendments. In 2009, Congress amended the FCA's reverse-claim provision to make clear that a defendant's knowing failure to repay an "overpayment" constitutes an FCA violation. Specifically, section (a)(1)(G) of the amended statute applies to anyone who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." "Obligation" is specifically defined to mean "an established duty" arising from "statute or regulation, or from the retention of any overpayment." 31 U.S.C. § 3729(b)(3) (emphasis added). The amendment also removed the requirement of a "false record or statement," which this Court pointed to in *Novartis V*. 2004 WL 4370597, at *30.

September 19, 2014 Page 2

Defendants also ignore the Medicare and Medicaid Program Integrity Provisions, which were enacted by the Patient Protection and Affordable Care Act (PPACA), and took effect on March 23, 2010. 42 U.S.C. § 1320a-7k. As Relator alleges in his Third Amended Complaint, these provisions place an affirmative duty on health care providers to report **and return** any Medicare or Medicaid overpayments within 60 days of discovery. Third Amend. Compl. ¶¶ 73-74, 159 (citing 42 U.S.C. § 1320a-7k(d)(2)). To remove any doubt, the Program Integrity Provisions expressly cite the FCA, and state that the duty to return an overpayment "is an obligation (as defined in [the FCA]) for purposes of [the FCA]." 42 U.S.C. § 1320a-7k(d)(3); Third Amend Compl. ¶74.

These provisions define "overpayment" broadly to include the conduct alleged here: An "overpayment" is "<u>any</u> funds that a person receives <u>or retains</u> under subchapter XVIII [Medicare] or XIX [Medicaid] <u>to which the person, after applicable reconciliation, is not entitled</u>." 42 U.S.C. § 1320a-7k(d)(4)(B) (emphasis added). Therefore, a provider who retains a payment for a Medicare or Medicaid service, <u>knowing</u> that he or she "is not entitled" to that payment because the service was tainted by a kickback, violates the reverse-claim provision of the FCA.

A recent case, decided under the amended statutes cited in Relator's Third Amended Complaint, disproves the defendants' argument that the two provisions are redundant. *United States v. Lakeshore Med. Clinic, Ltd.*, 11-CV-00892, 2013 WL 1307013, at *2-*4 (E.D. Wis. Mar. 28, 2013) (relator's allegations of overbilling stated claim under both the false claim and reverse-claim provisions). The same case holds that, even if the pleading or proof is insufficient to show that a particular claim for reimbursement was false under the direct FCA provision, (a)(1)(A), that same claim may later give rise to FCA liability on the reverse-claim provision, (a)(1)(G), once the defendant knows (or should have known) of the original falsity. *Id.* *5 (claim for overbilling for physician's assistant services fails under (a)(1)(A) but survives under (a)(1)(G) because "defendant took no action to correct" its earlier false claims once it had reason to know of the improper billing practices).

While defendants cite a number of cases in their brief, not one of these cases even cites, much less discusses, the Program Integrity Provisions added in March 2010. These provisions satisfy the precise deficiency that defendants' cases pointed to in dismissing those relators' reverse-claim allegations, the lack of a cognizable "obligation" to restore funds to the government. *E.g.*, *Chesbrough v. VPA*, *P.C.*, 655 F.3d 461, 473 (6th Cir. 2011) (dismissing reverse claim because "The Chesbroughs have not identified in their complaint any concrete obligation

September 19, 2014 Page 3

owed to the government by VPA"); *United States ex rel. Sobek v. Educ. Mgmt.*, LLC, CIV.A. 10-131, 2013 WL 2404082 (W.D. Pa. May 31, 2013) (dismissing reverse claim because "Relator fails to identify the statute, regulation or provision of the PPAs that obligates Defendants to repay monies improperly obtained because of false certification"); *United States v. HCA Health Servs. of Oklahoma, Inc.*, 3:09-CV-0992, 2011 WL 4590791 (N.D. Tex. Sept. 30, 2011) (dismissing reverse claim because "Defendants did not have an existing obligation to reimburse the monies it had received from Medicare because the government has never imposed any obligation on Defendants to reimburse any Medicare payments").

Defendants also argue that Relator's reverse FCA claim is "redundant" of the other claims, but that is untrue. To give just one example, assume that a provider was receiving kickbacks for a particular drug, and was submitting false claims for reimbursement for that drug, but did not have the requisite scienter, and thus is not liable under paragraph (a)(1)(A) of the FCA for those false claims. Assume further that the provider later learns additional information that gives the provider reason to know that the prior claims were false. That would establish scienter for subsequent claims that the provider submits—but what about the earlier claims, which the defendant now knows or suspects to be legally false? Under these circumstances, the defendant would be liable under the FCA's reverse-false-claims provision (for retaining the payment she was not entitled to), even though she was not liable for a FCA violation when the claim was originally submitted.

For these reasons, Relator's reverse FCA claim is not futile, and we pray that it be allowed to proceed.

Respectfully,

William Christopher Carmody

Cc: All Counsel (by ECF)

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